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(71) Applicant: **NITTO DENKO CORPORATION**
1-2, Shimohozumi 1-chome
Ibaraki-shi
Osaka (JP)

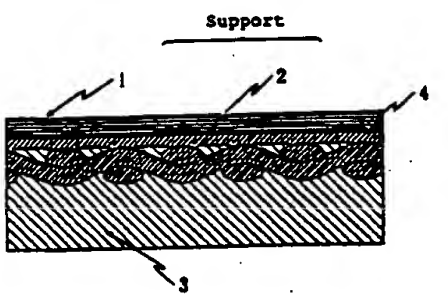
(72) Inventor: **Muraoka, Takateru, c/o Nitto Denko Corp.**
1-2, Shimohozumi 1-chome
Ibaraki-shi,
Osaka (JP)
Inventor: **Kinoshita, Takashi, c/o Nitto Denko Corp.**
1-2, Shimohozumi 1-chome
Ibaraki-shi,
Osaka (JP)
Inventor: **Akemi, Hitoshi, c/o Nitto Denko Corp.**
1-2, Shimohozumi 1-chome
Ibaraki-shi,
Osaka (JP)
Inventor: **Otsuka, Saburo, c/o Nitto Denko Corp.**
1-2, Shimohozumi 1-chome
Ibaraki-shi,
Osaka (JP)

(74) Representative: **Patentanwälte Grünecker, Kinkeldey, Stockmair & Partner**
Maximilianstrasse 58
D-80538 München (DE)

(54) Medical adhesive sheet.

(57) A medical adhesive sheet comprising a support having a laminate structure comprising a non-porous sheet and a porous-sheet, and a pressure-sensitive layer comprising an acrylic polymer prepared by polymerizing an alkyl (meth)acrylate as a main component monomer, and an organic liquid component which is compatible with the acrylic polymer, formed on the porous sheet side of the support, the layer being subjected to a crosslinking treatment, wherein the pressure-sensitive adhesive layer is embedded in the porous sheet, reaching the laminate interface between the non-porous sheet and the porous sheet. The medical adhesive sheet has improved anchoring property of its pressure-sensitive adhesive layer to the support while exhibiting a good balance between adhesion to the skin and low irritation to the skin.

FIGURE



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BRIEF DESCRIPTION OF THE DRAWING

The Figure is a cross section of a medical adhesive sheet according to the present invention, in which woven fabric is used as a porous sheet of the support.

DETAILED DESCRIPTION OF THE INVENTION

The pressure-sensitive adhesive layer in the medical adhesive sheet according to the present invention is a layer obtained by crosslinking a composition comprising an acrylic polymer obtained by polymerizing an alkyl (meth)acrylate as a main component monomer, and an organic liquid component compatible with the acrylic polymer. If the acrylic polymer is replaced with other polymeric materials or polymers, such as natural rubber, various synthetic rubbers and silicone resins, there is a tendency that the organic liquid component present in a relatively large proportion could not be retained in the pressure-sensitive adhesive layer due to lack of compatibility with these polymeric materials or polymers and would bloom to the surface during storage. Additionally, it is difficult to control the degree of crosslinking of the pressure-sensitive layer containing such polymeric materials or polymers. Where a drug is incorporated into the pressure-sensitive adhesive layer, polymeric materials or polymers other than the acrylic polymers are hardly useful because some drugs are given only a limited choice of the polymer matrix to be combined with, taking releasability or stability of the drug into consideration.

The alkyl (meth)acrylates which can be used as a main component monomer to obtain the above-described acrylic polymer include those having from 4 to 18 carbon atoms in the alkyl moiety thereof, such as butyl (meth)acrylate, pentyl (meth)acrylate, hexyl (meth)acrylate, heptyl (meth)acrylate, octyl (meth)-acrylate, nonyl (meth)acrylate, decyl (meth)acrylate, undecyl (meth)acrylate, dodecyl (meth)acrylate, and tridecyl (meth)acrylate. The alkyl moiety may be either a straight-chain alkyl group or a branched alkyl group. These alkyl (meth)acrylates are used, either individually or in combination of two or more thereof, in a proportion of at least 40% by weight, preferably 50 to 98% by weight, and still preferably from 60 to 98% by weight, based on the total monomers. If desired, part of the alkyl (meth)acrylate monomer(s) having 4 to 18 carbon atoms in the alkyl moiety thereof may be replaced with those having a lower alkyl group containing 3 or less carbon atoms, such as methyl (meth)acrylate, ethyl (meth)acrylate, and propyl (meth)-acrylate.

The acrylic polymer used in the present invention may be a copolymer obtained by copolymerizing the above-described alkyl (meth)acrylate monomer and a copolymerizable monomer, such as a polar monomer and/or a vinyl monomer.

Examples of suitable polar monomers include carboxyl-containing monomers, such as (meth)acrylic acid, itaconic acid, maleic acid, maleic anhydride, and crotonic acid; sulfoxy-containing monomers, such as styrenesulfonic acid, allylsulfonic acid, sulfopropyl (meth)acrylate, (meth)acryloyloxynaphthalenesulfonic acid, and acrylamidomethylpropanesulfonic acid; hydroxyl-containing monomers, such as hydroxyethyl (meth)acrylate and hydroxypropyl (meth)acrylate; amido-containing monomers, such as (meth)acrylamide, dimethyl(meth)acrylamide, N-butylacrylamide, N-methylol(meth)acrylamide, and N-methylolpropane(meth)-acrylamide; alkylaminoalkyl-containing monomers, such as aminoethyl (meth)acrylate, dimethylaminoethyl (meth)acrylate, and t-butylaminoethyl (meth)acrylate; alkoxyalkyl (meth)acrylates, such as methoxyethyl (meth)acrylate and ethoxyethyl (meth)acrylate; alkoxy-containing (meth)acrylic esters or (meth)acrylic esters containing an oxido bond in the side chain thereof, such as tetrahydrofurfuryl (meth)acrylate, methoxyethylene glycol (meth)acrylate, methoxydiethylene glycol (meth)acrylate, and methoxypolyethylene glycol (meth)acrylate; and (meth)acrylonitrile. These polar comonomers may be used either individually or in combination of two or more thereof.

Examples of suitable vinyl monomers include vinyl esters, such as vinyl acetate and vinyl propionate; and nitrogen-containing heterocyclic vinyl compounds, such as N-vinyl-2-pyrrolidone, methylvinylpyrrolidone, vinylpyridine, vinylpiperidone, vinylpyrimidine, vinylpiperazine, vinylpyrazine, vinylpyrrole, vinylimidazole, vinylcaprolactam, and vinyloxazole. These vinyl comonomers may be used either individually or in combination of two or more thereof.

Among the above-enumerated polar monomers and vinyl monomers preferred are carboxyl-containing monomers, hydroxyl-containing monomers, amido-containing monomers, alkoxyalkyl (meth)acrylates, alkoxy-containing (meth)acrylic esters, and (meth)acrylic esters containing an oxido bond in the side chain thereof; for they not only have such a functional group as becomes an active site in the subsequent crosslinking but also are effective to raise the glass transition temperature of an acrylic polymer to improve the cohesive force. From the viewpoint of improvement of a cohesive force and a dissolving power for a drug, if used, it is preferable to use vinyl esters, nitrogen-containing heterocyclic vinyl compounds, and the

the like in a total amount of from about 2 to 50 parts by weight per 100 parts by weight of the acrylic polymer.

The medical adhesive sheet having the above-described structure can contain in its pressure-sensitive adhesive layer a drug for percutaneous absorption either in a dissolved state or in a dispersed state to prepare a medical adhesive sheet which can be used for treatment and/or prevention of various diseases.

Drugs which can be incorporated into the adhesive layer include corticosteroids, analgetic antiinflammatory agents, hypnotic sedatives, tranquilizers, antihypertensives, hypotensive diuretics, antibiotics, anesthetics, antimicrobials, antifungals, vitamins, coronary vasodilators, antihistaminics, antitussives, sex hormones, antidepressants, cerebral circulation improving agents, antiemetics, antitumor agents, and biological preparations. If desired, these drugs may be used in combination of two or more thereof. In general, orally administered drugs undergo primary metabolism on the first pass effect through the liver, while injected drugs have a short duration. Accordingly, considering prevention of the first metabolism of a drug and long-lasting maintenance of an effective concentration in blood, those having a systemic action are preferred among the above-described drugs for percutaneous administration.

The content of the drug may be selected appropriately according to the kind of the drug or the purpose of administration and usually ranges from about 1 to 40% by weight, preferably from about 2 to 30% by weight, based on the weight of the adhesive layer. A drug content of less than 1% by weight cannot be expected to release the drug in a level sufficiently effective for the treatment or prevention of a disease. A drug content exceeding 40% by weight not only produces no further increase of the therapeutic or prophylactic effect but is uneconomical.

The medical adhesive sheet of the present invention comprises a support having formed on one side thereof the above-described adhesive layer as shown in the Figure. The support has a laminate structure composed of a non-porous sheet 1 and a porous sheet 2, and a pressure-sensitive adhesive layer 3 is formed on the side of the porous sheet 2 in such a manner that the pressure-sensitive adhesive layer 3 is embedded in the porous sheet 2, reaching the laminate interface between the non-porous sheet 1 and the porous sheet 2. It is desirable for obtaining a practical anchoring effect that the pressure-sensitive adhesive layer should be embedded in the porous sheet to such an extent that, when the non-porous sheet is forcedly detached from the porous sheet at the interface, the pressure-sensitive adhesive layer exposed on the non-porous sheet may have a peel strength of not less than 5 g/24 mm width, preferably not less than 8 g/24 mm width, in a peel test to a Bakelite plate at a rate of pulling of 300 mm/min, as tested in Examples hereinafter given. The terminology "non-porous sheet" as used herein means a sheet which has not been subjected to any positive hole-making treatment, such as perforation or expansion. The terminology "porous sheet" as used herein means a sheet which has been subjected to a positive treatment for making it porous or a sheet having through-pores, such as cloth.

The non-porous sheet which can be used in the present invention includes a sheet of various plastics, such as polyester, nylon, saran, polyethylene, polypropylene, polyvinyl chloride, polyvinylidene chloride, an ethylene-ethyl acrylate copolymer, an ethylene-vinyl acetate copolymer, an ethylene-vinyl alcohol copolymer, polytetrafluoroethylene, Surlyn, polyurethane, rayon, vinylon, acrylic resins, acetate, and triacetate; a metal-deposited plastic sheet, and a metal foil, either singly or in the form of a laminate of two or more of these sheets. Preferred of them are those having so-called non-strike through properties, i.e., impermeability to an organic liquid component or a drug contained in the adhesive layer, such as a sheet of polyester, polytetrafluoroethylene, polyethylene or polypropylene.

The porous sheet which can be used in the present invention includes a sheet obtained by subjecting the above-enumerated non-porous sheet to perforation or expansion to form open cells, a paper, a woven fabric, a nonwoven fabric, and a knitted fabric. A porous sheet comprising a nonwoven fabric or a woven fabric is preferred for sufficient embedment of the adhesive layer. In particular, the nonwoven or woven fabric having a basis weight of from 5 to 30 g/m^2, preferably from 8 to 20 g/m^2, is recommended for ensuring improved anchoring property of the pressure-sensitive adhesive layer.

The method of laminating the non-porous sheet and the porous sheet is not particularly limited and includes, for example, extrusion laminating, heat bonding under pressure, or lamination using a conventional adhesive, such as a polyester-based adhesive. To ensure lamination so as not to cause delamination at the laminate interface, lamination using an adhesive is preferred. The thickness of the support is not particularly limited. Taking into consideration the softness of the medical adhesive sheet on applying to the skin and the anchoring property between the pressure-sensitive adhesive layer and the porous sheet, it is recommended that the thickness of the non-porous sheet be from about 0.5 to 50 μm, preferably from about 1 to 25 μm, and that of the porous sheet be from about 10 to 500 μm, preferably from about 10 to 200 μm, totaling from about 11 to 550 μm, preferably from about 15 to 225 μm. While the thickness of the pressure-sensitive adhesive sheet is difficult to specify because it is embedded in the porous sheet, it usually ranges

EXAMPLE 3

A medical adhesive sheet was prepared in the same manner as in Example 1, except for replacing the aluminum tris(acetylacetonate) as a crosslinking agent with 1 part of dipropoxybis(acetylacetonato)titanium.

EXAMPLE 4

A drug-containing medical adhesive sheet was prepared in the same manner as in Example 1, except that the coating solution was prepared by mixing 50 parts of the solid content of the acrylic polymer with 40 parts of isopropyl myristate and 10 parts of Metoprolol and adding to the resulting mixture 0.8 part, per 100 parts of the solid content of the acrylic polymer, of aluminum tris(acetylacetonate).

EXAMPLE 5

A drug-containing medical adhesive sheet was prepared in the same manner as in Example 2, except that the coating solution was prepared by mixing 45 parts of the solid content of the acrylic polymer with 45 parts of isopropyl myristate and 10 parts of Ketoprofen and adding to the resulting mixture 0.3 part, per 100 parts of the solid content of the acrylic polymer, of a trifunctional isocyanate "Coronate HL", produced by Nippon Polyurethane Industry Co., Ltd.

EXAMPLE 6

A medical adhesive sheet was prepared in the same manner as in Example 2, except for replacing isopropyl myristate as an organic liquid component with diethyl sebacate.

EXAMPLE 7

A drug-containing medical adhesive sheet was prepared in the same manner as in Example 4, except for changing the solid content of the acrylic polymer and the amount of isopropyl myristate to 40 parts and 50 parts, respectively.

EXAMPLE 8

A drug-containing medical adhesive sheet was prepared in the same manner as in Example 5, except for replacing 45 parts of isopropyl myristate as an organic liquid component with a combination of 30 parts of isopropyl myristate and 15 parts of diethyl sebacate and increasing the amount of the trifunctional isocyanate to 0.35 part.

EXAMPLE 9

A drug-containing medical adhesive sheet was prepared in the same manner as in Example 4, except for replacing the 40 parts of isopropyl myristate with a combination of 25 parts of isopropyl myristate and 15 parts of diethyl sebacate.

COMPARATIVE EXAMPLE 1

The same coating solution as prepared in Example 1 was applied to a 75 μm thick polyester separator and dried to form a crosslinked pressure-sensitive adhesive layer having a dry thickness of 80 μm.

The thus formed pressure-sensitive adhesive layer was adhered to the nonwoven fabric side of the same support as used in Example 1 to prepare a medical adhesive sheet.

COMPARATIVE EXAMPLE 2

A medical adhesive sheet was prepared in the same manner as in Comparative Example 1, except for using 1 part, per 100 parts of the solid content of the acrylic polymer, of titanium acetoacetonate in place of 0.5 part of aluminum tris(acetylacetonate).

1) Application Test:

A cut piece of the medical adhesive sheet having an area of 5 cm^2 (22.5 mm × 22.5 mm) was applied to the skin of a human upper arm for 24 hours. For those samples containing a drug for percutaneous absorption, the amount of the drug which had migrated into the skin (hereinafter referred to as drug migration weight) was measured as a difference in drug content before and after the 24 hour application. After the 24 hour application, the medical adhesive sheet was peeled off the skin, and remaining of the adhesive layer on the skin due to anchoring failure was visually observed.

2) Confirmation of Embedment in Porous Sheet:

In order to confirm that the pressure-sensitive adhesive layer was embedded in the porous sheet to reach the laminate interface with the non-porous sheet, the separator was stripped off each sample, and a 12 μm polyester film having not been subjected to a release treatment was laminated on the exposed pressure-sensitive adhesive layer instead.

The resulting sample was cut to a 24 mm wide strip, and only the non-porous sheet was forcedly detached to expose the laminate interface of the porous sheet.

The thus exposed porous sheet side was adhered to a Bakelite plate by giving one stroke of a roller having a load of 300 g. Then, the whole medical adhesive sheet was peeled from the plate at a peel angle of 180° at a rate of pulling of 300 mm/min to measure the peel strength.

TABLE 1

Example No.	Remaining of Adhesive	Drug Migration Weight (μg)	Peel Strength of Embedded Adhesive Layer (g/24 mm width)
Example 1	none	-	16
Example 2	none	-	12
Example 3	none	-	15
Example 4	none	1250±136	20
Example 5	none	1485±216	14
Example 6	none	-	10
Example 7	none	1528±186	19
Example 8	none	1427±102	13
Example 9	none	1218±116	18
Comparative Example 1	observed	-	2
Comparative Example 2	observed	-	1
Comparative Example 3	observed	-	2
Comparative Example 4	none	596±127	5
Comparative Example 5	none	836±286	4
Comparative Example 6	observed	-	-
Comparative Example 7	observed	unmeasurable due to adhesive remaining	2
Comparative Example 8	observed	"	1
Comparative Example 9	observed	"	1
Comparative Example 10	observed	"	2

As is apparent from the results in Table 1, the medical adhesive sheet according to the present invention exhibits moderate adhesion to the skin as well as satisfactory anchoring property between the pressure-sensitive adhesive layer and the support. Where a drug for percutaneous absorption is incorporated into the pressure-sensitive adhesive layer, the pressure-sensitive adhesive layer shows high rate of drug migration to the skin, proving useful for percutaneous administration of the drug. To the contrary, the samples of Comparative Examples 1 to 3 and 7 to 10 were unsatisfactory for practical use in terms of anchoring property and adhesive remaining because the pressure-sensitive adhesive layer was not sufficiently embedded in the porous sheet.

of Bunitrolol and the crosslinking agent was not added. In this case, the pressure-sensitive adhesive layer did not contain the organic liquid component and was not crosslinked.

COMPARATIVE EXAMPLE 12

A drug-containing medical adhesive sheet, in which the pressure-sensitive adhesive layer thereof did not contain the organic liquid component and was not crosslinked, was prepared in the same manner as in Comparative Example 11, except that the coating solution was prepared from 85 parts of the solid content of the acrylic polymer and 15 parts of Bunitrolol.

COMPARATIVE EXAMPLE 13

The same coating solution as prepared in Example 10 was applied to a 25 μm thick, non-porous polyester film and dried to form a crosslinked pressure-sensitive adhesive layer having a dry thickness of 80 μm.

A 75 μm thick polyester separator was laminated on the pressure-sensitive adhesive layer to prepare a drug-containing medical adhesive sheet.

COMPARATIVE EXAMPLE 14

The same coating solution as prepared in Example 10 was applied to a 75 μm thick polyester separator and dried to form a crosslinked pressure-sensitive adhesive layer having a dry thickness of 80 μm.

The resulting pressure-sensitive adhesive layer was adhered to the non-woven fabric side of the same support as used in Example 10 to prepare a drug-containing medical adhesive sheet.

COMPARATIVE EXAMPLE 15

A drug-containing medical adhesive sheet was prepared in the same manner as in Comparative Example 14, except for adding 1.5 parts of acetoacetonatotitanium to 100 parts of the solid content of the acrylic polymer.

COMPARATIVE EXAMPLE 16

A drug-containing medical adhesive sheet was prepared in the same manner as in Comparative Example 14, except for replacing isopropyl myristate as an organic liquid component with diethyl sebacate.

COMPARATIVE EXAMPLE 17

A drug-containing medical adhesive sheet was prepared in the same manner as in Comparative Example 14, except for changing the amounts of the acrylic polymer and isopropyl myristate to 40 parts and 50 parts, respectively.

COMPARATIVE EXAMPLE 18

A drug-containing medical adhesive sheet was prepared in the same manner as in Comparative Example 14, except for replacing the isopropyl myristate as an organic liquid component with a combination of 25 parts of isopropyl myristate and 15 parts of diethyl sebacate.

Each of the drug-containing medical adhesive sheets obtained in Examples 10 to 18 and Comparative Examples 11 to 18 was evaluated in the same manner as described above. The results obtained are shown in Table 2 below.

4. A medical adhesive sheet as claimed in Claim 3, wherein said polar monomer is at least one compound selected from the group consisting of (meth)acrylic acid, a hydroxyalkyl (meth)acrylate, (meth)-acrylamide, and an alkoxyalkyl (meth)acrylate.

5. A medical adhesive sheet as claimed in Claim 2, wherein said vinyl monomer is at least one compound selected from the group consisting of vinyl acetate, vinyl propionate, and N-vinyl-2-pyrrolidone.

6. A medical adhesive sheet as claimed in Claim 1, wherein said organic liquid component is at least one compound selected from the group consisting of alcohols, glycols, fats and oils, organic solvents, long chain fatty acids, long chain fatty acid monoalkyl esters, long chain fatty acid dialkyl esters, and surface active agents.

7. A medical adhesive sheet as claimed in Claim 1, wherein said organic liquid component is present in an amount of from 25 to 200 parts by weight per 100 parts by weight of said acrylic polymer.

8. A medical adhesive sheet as claimed in Claim 7, wherein said organic liquid component is present in an amount of from 40 to 180 parts by weight per 100 parts by weight of said acrylic polymer.

9. A medical adhesive sheet as claimed in Claim 8, wherein said organic liquid component is present in an amount of from 60 to 180 parts by weight per 100 parts by weight of said acrylic polymer.

10. A medical adhesive sheet as claimed in Claim 1, wherein said crosslinking is carried out by addition of a crosslinking agent or through copolymerization of a polyfunctional monomer.

11. A medical adhesive sheet as claimed in Claim 10, wherein said crosslinking agent is at least one compound selected from the group consisting of a metal alcoholate, a metal chelate compound, and a polyfunctional isocyanate.

12. A medical adhesive sheet as claimed in Claim 1, wherein said non-porous sheet is a plastic sheet, a metal foil, a metal-deposited plastic sheet, or a laminate sheet composed of a plastic sheet and a metal foil.

13. A medical adhesive sheet as claimed in Claim 1, wherein said non-porous sheet has a thickness of from 1 to 25 μm.

14. A medical adhesive sheet as claimed in Claim 1, wherein said porous sheet is a paper, a woven fabric, a nonwoven fabric, a knitted fabric or a combination thereof.

15. A medical adhesive sheet as claimed in Claim 1, wherein said porous sheet has a basis weight of from 5 to 30 g/m^2.

16. A medical adhesive sheet as claimed in Claim 1, wherein said laminate sheet comprising a non-porous sheet and a porous sheet is prepared by laminating the non-porous sheet and the porous sheet via an adhesive.

17. A medical adhesive sheet as claimed in Claim 1, wherein said pressure-sensitive adhesive layer further contains a drug for percutaneous absorption.

18. A medical adhesive sheet as claimed in Claim 17, wherein said drug has a systemic action.

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(71) Applicant: **NITTO DENKO CORPORATION**
1-2, Shimohozumi 1-chome
Ibaraki-shi
Osaka (JP)

(72) Inventor: **Muraoka, Takateru, c/o Nitto Denko Corp.**
1-2, Shimohozumi 1-chome
Ibaraki-shi,
Osaka (JP)
Inventor: **Kinoshita, Takashi, c/o Nitto Denko Corp.**
1-2, Shimohozumi 1-chome
Ibaraki-shi,
Osaka (JP)
Inventor: **Akemi, Hitoshi, c/o Nitto Denko Corp.**
1-2, Shimohozumi 1-chome
Ibaraki-shi,
Osaka (JP)
Inventor: **Otsuka, Saburo, c/o Nitto Denko Corp.**
1-2, Shimohozumi 1-chome
Ibaraki-shi,
Osaka (JP)

(74) Representative: **Patentanwälte Grünecker, Kinkeldey, Stockmair & Partner**
Maximilianstrasse 58
D-80538 München (DE)

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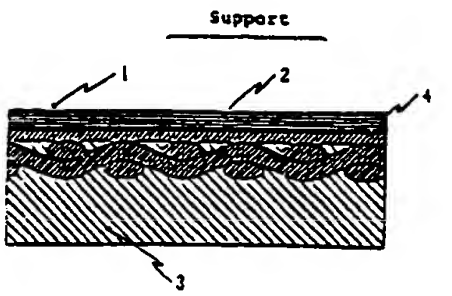
FIGURE



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